

PATENT COOPERATION TREATY

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REC'D 11 JUL 2005

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 60517-PCT	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US03/41127	International filing date (day/month/year) 26 December 2003 (26.12.2003)	Priority date (day/month/year) 27 December 2002 (27.12.2002)	
International Patent Classification (IPC) or national classification and IPC IPC(7): C12Q 1/68; C07H 21/04 and US Cl.: 435/6. 91.2; 536/23.1, 24.3			
Applicant THE JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of ____ sheets.</p> <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input checked="" type="checkbox"/> Certain observations on the international application 			
Date of submission of the demand 27 July 2004 (27.07.2004)		Date of completion of this report 27 June 2005 (27.06.2005)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer Sally Sakelaris <i>Janice Ford</i> Telephone No. 571-272-1600 <i>for</i>	

Form PCT/IPEA/409 (cover sheet)(July 1998)

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-30 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____.
- ☒ the claims:
pages 31-34 as originally filed
pages NONE as amended (together with any statement) under Article 19
pages NONE filed with the demand
pages NONE filed with the letter of _____.
- ☒ the drawings:
pages 1-17 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____.
- ☐ the sequence listing part of the description:
pages NONE as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

Novelty (N)	Claims <u>NONE</u>	YES
	Claims <u>1-6</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-6</u>	NO
Industrial Applicability (IA)	Claims <u>1-6</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-6 lacks an inventive step under PCT Article 33(3) as being obvious over Rischewski et al.(J Biochem . Biophys. Methods 47(2001) 53-64.

With regard to claim 1-6, Rischewski et al. teach a method of screening for a highly polymorphic gene and specifically DHPLC analysis of the Fanconi anemia group A gene.

Claims 1-6 meet the criteria set out in PCT Article 33(4), and thus has industrial applicability because the subject matter claimed can be made or used in industry.

----- NEW CITATIONS -----

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.

PCT/US03/41127

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claim 1-6 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claim 1-6 are indefinite for the following reason(s): Claim 1's recitation of a "cancer associated" coding change is indefinite as it is unclear how the change is associated with cancer, is it of predictive value, a consequence of a mutation, etc. Appropriate correction is suggested.

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
GREGORY B. BUTLER
EDWARDS & ANGELL, LLP
P.O. BOX 55874
BOSTON, MA 02205

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COMMUNICATION IN CASES FOR WHICH
NO OTHER FORM IS APPLICABLE

Date of Mailing (day/month/year)	
Applicant's or agent's file reference 60517-PCT	REPLY DUE see paragraph 1 below
International application No. PCT/US03/41127	International filing date (day/month/year) 26 December 2003 (26.12.2003)
Applicant THE JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE	

1. ☐ REPLY DUE within ____ months/days from the above date of mailing

☐ NO REPLY DUE

2. COMMUNICATION:

See attached 428.

Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Sally Sakelaris <i>Janice Ford</i> Telephone No. 571-272-1600
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PATENT COOPERATION TREATY

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NOTE OF INFORMAL COMMUNICATION WITH THE APPLICANT

(PCT Rule 66.6)

International application No. PCT/US03/41127	Applicant's or agent's file reference 60517-PCT	Date of informal communication (day/month/year) 23 June 2005 (23.06.2005)
Applicant THE JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE		

<u>Communication</u> <input checked="" type="checkbox"/> by telephone <input type="checkbox"/> personal	<u>Participants</u> <input checked="" type="checkbox"/> Applicant: THE JOHNS HOPKINS UNIV SCHOOL OF MEDICINE <input checked="" type="checkbox"/> Agent: Greg Butler <input checked="" type="checkbox"/> Examiner(s): Sally Sakelaris	<input checked="" type="checkbox"/> Identity checked <input type="checkbox"/> authorization checked <input type="checkbox"/> personally known
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Summary of communication:

It was agreed upon that the 408(Written Opinion) would be waived and a 409 (International Preliminary Examination Report) would be prepared and mailed. Mr. Butler acknowledged that waiving the 408 resulted in the loss of right to respond to the 408.

☐ An extension of time limit is granted (Form PCT/IPEA/427).

☒ A copy of this note is being sent to the applicant with Form PCT/IPEA/429.

PCT/IPEA/424.

Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Sally Sakelaris Telephone No. 571-272-1600
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Form PCT/IPEA/428 (July 1992)